## 410-124-000 TRANSPLANT SERVICES

- 1. The Office of Medical Assistance Programs (OMAP) will make payment for prior-authorized and emergency transplant services identified in these rules as covered for eligible clients receiving the Basic Benefit Health Care Package and when OMAP transplant criteria described in OAR 410-124-010 and 410-124-060 through 410-124-160 is met. Clients receiving the Limited Benefit Package are not eligible for transplant services; these clients are only eligible for mental health, alcohol/drug, pharmacy and medical transportation services. All transplants require prior authorization, except for kidney and cornea, which require prior authorization only if performed out-of-state.
- 2. The following types of transplants and transplant-related procedures are covered under the Medical Assistance program:
  - (a) Bone Marrow, Autologous and Allogeneic,
  - (b) Bone Marrow Harvesting and Peripheral Stem Cell Collection, Autologous,
  - (c) Cord blood, Allogeneic,
  - (d) Cornea,
  - (e) Heart,
  - (f) Heart-Lung,
  - (g) Kidney,
  - (h) Liver,
  - (i) Liver-Kidney,
  - (j) Simultaneous Pancreas and Kidney transplants, and Pancreas after Kidney transplants,
  - (k) Peripheral Stem Cell, Autologous and Allogeneic
  - (1) Single Lung,
  - (m) Bilateral Lung,
  - (n) Any other transplants the Health Services Commission and the Oregon Legislature determine are to be added to the Prioritized List of Health Services.

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### 3. Not Covered Transplant Services

The following types of transplants are not covered by the Oregon Medical Assistance program:

- (a) Any transplants not listed in subsection (2) of this rule.
- (b) Transplants which are considered experimental or investigational or which are performed on an experimental or investigational basis, as determined by OMAP.
- (c) Transplant services which are contraindicated, as described in 410-124-060 through 410-124-160.

### 4. Selection of Transplant Centers

Transplant services will be reimbursed only when provided in a transplant center which provides quality services, demonstrates good patient outcomes and compliance with all OMAP facility criteria. The transplant center must have provided transplant services for a period of at least two years and must have completed a minimum of 12 cases in the most recent year. The patient- and graft-survival rates must be equal to or greater than the appropriate standard indicated in this rule. A transplant center which has had at least two years of experience in transplantation of any solid organ (heart, liver, lung, pancreas) and which has met or exceeded the appropriate standards, may be considered for reimbursement for the transplantation of other solid organs and/or autologous or allogeneic bone marrow transplantation.

- (a) An experienced and proficient transplant team and a well established transplant support infrastructure at the same physical location as the transplant service is required for transplant services rendered to OMAP clients. These transplant criteria are crucial to successful transplant outcome. Therefore, consortia will not be approved or contracted with for the provision of transplant services for OMAP clients. No OMAP transplant contract, prior approval or reimbursement will be made to consortia for transplant services where, as determined by OMAP, there is no assurance that the individual facilities that make up the consortia independently meet OMAP criteria. OMAP transplant criteria must be met individually by a facility to demonstrate substantial experience with the procedure.
- (b) Once a transplant facility has been approved and contracted for OMAP transplant services, it is obliged to report immediately to OMAP any events or changes that would affect its approved status. Specifically, a transplant facility is required to report, within a reasonable period of time, any significant decrease in its experience level or survival rates, the departure of key members of the transplant team or any other major changes that could affect the performance of transplants at the facility. Changes from the terms of approval may lead to prospective withdrawal of approval for OMAP coverage of transplants performed at the facility.

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- (c) FCHPs without OMAP stop-loss that contract with non-OMAP contracted facilities for Basic Health Care Package clients will develop and use appropriate transplant facility criteria to evaluate and monitor for quality services at the transplant facility.
- (d) Transplant centers which have less than two years experience in solid organ transplant may be reimbursed, at OMAP's discretion, for allogeneic or autologous bone marrow transplants upon completion of two years of experience in bone marrow transplantation with patient survival rates equal to or exceeding those defined in section (5) of this rule.
- (e) OMAP will discontinue the contract with a transplant center when the graft and/or survival rates fall below the standards indicated in this rule for a period of two consecutive years.
- 5. Standards for Transplant Centers:
  - (a) Heart, heart-lung and lung transplants:
    - (1) Heart: one-year patient survival rate of at least 80%.
    - (2) Heart-lung: One-year patient survival rate of at least 65%.
    - (3) Lung: One-year patient survival rate of at least 65%.
  - (b) Bone Marrow (autologous and allogeneic), Peripheral Stem Cell (autologous and allogeneic), and cord blood (allogeneic) transplants:
    - (1) one-year patient survival rate of at least 50%.
  - (c) Liver and liver-kidney transplants:
    - (1) one-year patient survival rate of 70% and a one year graft survival rate of 60%.
  - (d) Simultaneous pancreas-kidney and pancreas-after-kidney transplants:
    - (1) one-year patient survival rate of 90% and one year graft survival rate of 60%.
- 6. Selection of transplant centers by geographic location
  - (a) If the services are available in the state of Oregon, reimbursement will not be made to out-of-state transplant centers. Out-of-state centers will be considered only if:
    - (1) the type of transplant required is not available in the state of Oregon and/or the type of transplant (for example, liver transplant) is available in the state of Oregon but the Oregon transplant center does not provide that type of transplant for all clients or all covered

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- (2) an in-state transplant center requests the out-of-state transplant referral, and
- (3) an in-state transplant facility recommends transplantation based on in-state facility and OMAP criteria, or
- (4) it would be cost effective as determined by OMAP. For example, if the transplant service is covered by the client's benefit package and the client's primary insurer (i.e., Medicare) requires the use of an out-of-state transplant center.
- 7. Professional and other services will be covered according to administrative rules in the applicable provider guides.
- 8. Covered Transplant services are transplants which:
  - (a) are described in OAR 410-124-000(2) and have been prior authorized for payment by OMAP, or the client's managed health care plan, or
  - (b) meet the guidelines for an emergency transplant (OAR 410-124-040).
- 9. Non-Covered Transplant services are transplants and transplant related services which:
  - (a) are not described in this guide in OAR 410-124-000(2) or
  - (b) are described in this guide in OAR 410-124-000(3) or
  - (c) have not been prior authorized for payment by OMAP or the client's managed health care plan, or
  - (d) do not meet the guidelines for an emergency transplant in OAR 410-124-040 or
  - (e) are not described as covered in OAR 410-141-480.

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# 410-124-020 PRIOR AUTHORIZATION FOR ALL COVERED TRANSPLANTS, EXCEPT CORNEA AND KIDNEY

- 1. Prior authorization is required as follows:
  - (a) All non-emergency transplant services require prior authorization of payment.
  - (b) Pre-transplant evaluations provided by the transplant center require prior authorization. Prior Authorization will only be made for evaluations for covered transplants.
- 2. The prior authorization request for all covered transplants is initiated by the client's in-state referring physician. The initial request should contain all available information outlined in subsection (3) of this rule, below.
  - (a) For fee-for-service and PCCM clients, the request should be sent to OMAP:

Office of Medical Assistance Programs Medical Director's Office/Transplants Human Resources Building, 3rd Floor 500 Summer St NE Salem, Oregon 97310-1014

Telephone: 503-945-6488 Facsimile: 503-373-7689

- (b) For clients enrolled in an FCHP, requests for transplant services other than lung or heart/lung transplants for the diagnosis of emphysema should be sent directly to the FCHP.
- (c) Prior authorization for lung or heart/lung transplants for the diagnosis of emphysema shall always be obtained from OMAP regardless of managed care enrollment.
- 3. A completed request for authorization must contain the following information. Failure to submit all the information will delay processing of the request. An optional form is provided at the end of this Transplant Services guide for provider convenience in submitting the request.
  - (a) The name, age, Medical Assistance I.D. number, and birth date of the client,
  - (b) A description of the medical condition and full ICD-9 coding which necessitates a transplant,
  - (c) The type of transplant proposed, with CPT code,
  - (d) The results of a current HIV test (completed within 6 months of request for transplant authorization),

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- (e) Any other evidence of contraindications for the type of transplant being considered (see contraindications under each transplant type),
- (f) The client's prognosis, with and without a transplant, including estimated life expectancy with and without the transplant,
- (g) Transplant treatment alternatives:
  - (1) A history of other treatments which have been tried,
  - (2) Treatments that have been considered and ruled out, including discussion of why they have been ruled out.
- (h) An evaluation based upon a comprehensive examination completed by a board certified specialist in a field directly related to the condition of the client which necessitates the transplant.
- (i) If already done before requesting prior authorization, the results of any medical and/or social evaluation completed by a transplant center should be included in the prior authorization request. The completion of an evaluation by a transplant center before receiving prior authorization from the Office of Medical Assistance Programs does not obligate the Office of Medical Assistance Programs to reimburse that transplant center for the evaluation or for any other transplant services not prior authorized.
- 4. Prior authorization approval process and requirements:
  - (a) For clients receiving services on a fee-for-service basis and/or enrolled with a PCCM:
    - (1) After receiving a completed request, OMAP will notify the referring physician within two weeks if an evaluation at a transplant center is approved or denied.
    - (2) A final determination for the actual transplant requires an evaluation by a selected transplant center, which will include:
      - (A) a medical evaluation,
      - (B) an estimate of the client's motivation and ability, both physical and psychological, to adhere to the post-transplant regimen,
      - (C) the transplant center's assessment of the probability of a successful outcome, based on the type of transplant requested, the condition of the client, and the client's ability to adhere to the post-transplant regimen, and
      - (D) a recommendation using both the transplant center's own criteria, and the Oregon Medical Assistance Program's criteria.

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- (b) For OHP transplant eligible clients who are in a fully capitated health plan (FCHP):
  - (1) Refer to the managed care plan for approval process and requirements.
- (c) The prior authorization request will be approved if:
  - (1) All OMAP criteria are met, and
  - (2) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized.
  - (3) The transplant service/diagnosis is covered under the Prioritized List of Health Services.
- 5. The referring physician, Transplant Center, and the client will be notified in writing by OMAP or the FCHP of the prior authorization decision.
- 6. Prior authorization of a transplant does not guarantee reimbursement for the services of any provider if, at the time the transplant is performed, intercurrent events have caused the individual's medical condition to deteriorate to the point at which survival with or without transplant for a period of more than sixty days is unlikely.

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### 410-124-040 EMERGENCY TRANSPLANTS

- 1. An Emergency Transplant is one in which medical necessity requires that a covered transplant be performed less than 5 days after determination of the need for a transplant.
- 2. Emergency transplants are subject to post-transplant review of the client's medical records by OMAP (or the managed care plan for clients enrolled in a fully capitated health plan) to determine if the client and the transplant center met the criteria in these rules at the time of the transplant. Related charges, including transportation, physician's services, and donor charges will be covered if payment is approved. OMAP will make payment as described in OAR 410-124-000(10) for OMAP covered transplants. Managed care plans will make payment as described in their contract with the transplant center.

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### 410-124-060 CRITERIA AND CONTRAINDICATIONS FOR HEART TRANSPLANTS

- 1. The client must have a maximum probability of a successful clinical outcome, i.e., the probability of the client's survival for a period of five years or more subsequent to the transplant must be at least 25 percent.
- 2. Coverage for transplantation is based on the OHP Prioritized List of Health Services.
- 3. A client considered for a heart transplant must have one of the following diagnoses:
  - (a) Heart failure, NYHA Class IV, or, rapidly progressive (over months) NYHA Class III.
  - (b) Progressive but reversible pulmonary hypertension with heart failure, such that delay of transplantation would result in irreversibility and the inability to perform heart transplantation at a later time.
  - (c) Heart disease with intractable ventricular arrhythmias not responsive to either medical or surgical therapy.
- 4. A client considered for a heart transplant must have a poor prognosis, i.e. less than a 50% chance of survival for one year without a transplant as a result of poor cardiac functional status or cardiac/pulmonary functional status.
- 5. All alternative medically accepted treatments that have a one year survival rate comparable to that of heart transplantation must have been tried or considered.
- 6. Requests for transplant services for children suffering from early congenital heart disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.
- 7. A client with one or more of the following contraindications is ineligible for heart transplant services:
  - (a) untreatable systemic vasculitis,
  - (b) incurable malignancy,
  - (c) diabetes with end-organ damage,
  - (d) active infection which will interfere with the client's recovery,
  - (e) refractory bone marrow insufficiency,
  - (f) irreversible renal disease,

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(d)	unresolved or continuing thromboembolic disease or pulmonary infarction,
(e)	serious psychological disorders,
(f)	drug or alcohol abuse,
(g)	irreversible pulmonary hypertension.
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The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe

the following condition(s) may interfere significantly with the recovery process:

significant cerebro-, or peripheral vascular disease,

(g)

(a)

(c)

irreversible hepatic disease,

(h) HIV positive test results.

hyperlipoproteinemia,

(b) curable malignancy,